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gestation),” and for use as top-dressing for individual treatment of adult swine. The supplemental NADA is approved as of August 10, 1998, and the regulations are amended in § 558.300 (21 CFR 558.300) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.300 is amended by redesignating paragraph (c) as paragraph (d), adding new paragraph (c), and in newly redesignated paragraph (d) inserting several editorial and technical changes and adding a required limitation statement.

This supplemental NADA is for use of approved ivermectin Type A medicated articles to make Type B and C medicated feeds. Ivermectin is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved medicated feed application is required for making Type B or C medicated feeds as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by the requirement for feed mill licenses. Therefore, use of ivermectin Type A medicated articles to make Type B and C medicated feeds as provided in this NADA is limited to manufacture in a licensed feed mill.

Also, the regulation concerning tolerances for ivermectin residues in edible tissues is amended to provide for an acceptable daily intake (ADI) for total ivermectin residues. The ADI is the amount of total drug residue that can be safely consumed by humans every day. Previously, FDA had codified safe concentrations for drug residues. The safe concentrations were confusing because few individuals understood the relationship between safe concentrations, a value representing total residues, and tolerances, the part of the drug residue in a given tissue that is detected by a specific analytical method. To eliminate this confusion, FDA is codifying the ADI.

In addition, the regulations for tolerances for ivermectin residues is further amended to establish a tolerance for ivermectin residues in swine muscle.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 10, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use in swine for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation).

FDA has determined under 21 CFR 25.33(a)(1) and (a)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.344 is revised to read as follows:

§ 556.344 Ivermectin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

(b) *Tolerances*—(1) *Liver*. A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in liver (target tissue) as follows:

- (i) *Cattle*. 100 parts per billion.
- (ii) *Swine*. 20 parts per billion.
- (iii) *Sheep*. 30 parts per billion.
- (iv) *Reindeer*. 15 parts per billion.
- (v) *American bison*. 15 parts per billion.

(2) *Muscle*. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in muscle as follows:

- (i) *Swine*. 20 parts per billion.
- (ii) [Reserved]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.300 is amended by redesignating paragraph (c) as paragraph (d), by adding new paragraph (c) and reserving it, ^{by adding introductory text to newly redesignated paragraph (d),} and by revising newly redesignated paragraph (d)(1), to read as follows:

§ 558.300 Ivermectin.

* * * *

(c) [Reserved]

(d) *Conditions of use.* It is used in swine feed as follows:

(1) *Amount per ton.* For weaned, growing-finishing swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, feed 1.8 to 11.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, may be top-dressed on daily ration for individual treatment at levels of 18.2 to 1180 grams (to provide 0.1 milligram per kilogram of body weight per day).

(i) *Indications for use.* For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum spp.*, adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus spp.*, adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).

(ii) *Limitations.* For use in swine feed only. Feed as sole ration for 7 consecutive days. Withdraw 5 days before slaughter. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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Dated: 9/28/98
September 28, 1998

Margaret Ann Miller
Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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